

CLOSED, ECF, JURY, TDIS

**U.S. District Court
Northern District of Texas (San Angelo)
CIVIL DOCKET FOR CASE #: 6:08-cv-00017
Internal Use Only**

Gomez v. Merck & Co Inc
Assigned to: Judge Sam R Cummings
Cause: 28:1332 Diversity-Product Liability

Date Filed: 04/08/2008
Date Terminated: 06/02/2008
Jury Demand: Both
Nature of Suit: 365 Personal Inj. Prod.
Liability
Jurisdiction: Diversity

Plaintiff

Tommie L Gomez
Individually

represented by **Austin Winters Anderson**
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V.

Defendant









Merck & Co Inc
a New Jersey Corporation






represented by **Richard L Josephson**
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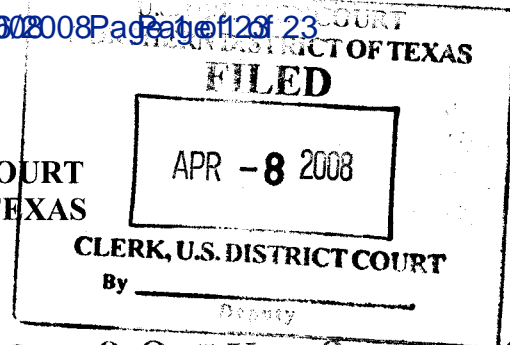
Certified a true copy of an instrument
on file in my office on 6/2/2008
Clerk, U.S. District Court,
Northern District of Texas
By [Signature] Deputy

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Date Filed	#	Docket Text
04/08/2008	 <u>1</u>	COMPLAINT WITH JURY DEMAND against Merck & Co Inc filed by Tommie L Gomez. (Filing fee \$350; Receipt number SA000378) (blr) (Entered: 04/08/2008)
04/08/2008	 <u>2</u>	Summons Issued as to Merck & Co Inc. (blr) (Entered: 04/08/2008)
04/08/2008	 <u>3</u>	Order Designating Case for ECF - see order for specifics. (Signed by Judge Sam R Cummings on 9/1/2006) (blr) (Entered: 04/08/2008)
04/11/2008	 <u>4</u>	CERTIFICATE OF INTERESTED PERSONS/DISCLOSURE STATEMENT by Tommie L Gomez. (Barrientos, Joseph) (Entered: 04/11/2008)
04/30/2008	 <u>5</u>	ANSWER to <u>1</u> Complaint by Merck & Co Inc (Josephson, Richard) (Entered: 04/30/2008)
04/30/2008	 <u>6</u>	(Court only) ***Attorney W Zachary Hughes for Merck & Co Inc added. (tmd) (Entered: 05/01/2008)
05/01/2008	 <u>6</u>	INITIAL SCHEDULING ORDER: Amended Pleadings due by 3:00 p.m. 8/15/2008. Joinder of Parties due by 3:00 p.m. 8/15/2008. Discovery due by 3:00 p.m. 3/16/2009. Motions 3:00 p.m. due by 3/16/2009; Experts must be disclosed by 3:00 p.m. 11/14/2008; Deadlines not extended except upon good cause & by order of Court; Unless further ordered by Court, parties not required to make initial disclosures under Rule 26(a)(1) FedRCivP; No conferences required under Rule 26(f) FedRCivP; Counsel must strictly comply with mandates set forth in Dondi. Counsel are referred to the Standing Order Designating Case for Enrollment in the Electronic Case Files ECF System; Filing documents electronically is not mandatory; In all cases where electronic case filing is permitted, counsel may serve and respond to written discovery requests through electronic mail service; this discovery practice will be governed by ND/TX Local Rules and this Courts Local Rules regarding electronic case filing procedures; Counsel are referred to Local Rules ND/TX, Civil Justice Cost & Delay Reduction Plan ND/TX, & Local Rules of this Court. Parties will be notified by separate order of date of trial and date for filing proposed pretrial order. (Signed by Judge Sam R Cummings on 5/1/2008) (tmd) (Entered: 05/01/2008)
05/21/2008	 <u>7</u>	Order Directing Administrative Closure - Court notified that conditional transfer order filed in MDL-1789, In re Fosamax Products Liability Litigation to Southern District of New York became effective; Cause administratively closed w/out prejudice to its being reopened if case is transferred back to this

		Court. (Signed by Judge Sam R Cummings on 5/21/2008) (tmd) (Entered: 05/21/2008)
05/22/2008	 <u>8</u>	Receipt of courtesy copy of conditional transfer order from U.S. Judicial Panel on Multidistrict Litigation, Case No. MDL No. 1789 -- IN RE: Fosamax Products Liability Litigation (tmd) (Entered: 05/22/2008)
06/02/2008		***Case Reopened to enter Conditional Transfer Order (CT0-54) transferring case to the Southern District of New York (blr) (Entered: 06/02/2008)
06/02/2008	 <u>9</u>	Order Transferring to Another District: Case transferred to Judicial Panel on Multidistrict Litigation - MDL No. 1789, In Re: Fosamax Products Liability Litigation of Southern District of New York (filed by SD/NY on 5/22/2008; filed by Clerk of the Panel for the Panel on 5/1/2008.) (Attachments: # <u>1</u> Letter) (blr) (Entered: 06/02/2008)
06/02/2008		Interdistrict Transfer to SD/NY, MDL No. 1789, In Re: Fosamax Products Liability Litigation (blr) (Entered: 06/02/2008)
06/02/2008	 <u>10</u>	Letter to SD/NY, MDL 1789, In Re: Fosamax Products re: Case Transferred Out - District Transfer forwarding certified copy of Docket Sheet and and transmittal letter from SD/NY (blr) (Entered: 06/02/2008)



IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
SAN ANGELO DIVISION

TOMMIE L. GOMEZ, Individually,

Plaintiff,

v.

MERCK & CO. INC., a New Jersey
Corporation,

Defendant.

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Civil Action No.: 6 08 CV - 017 - C

JURY TRIAL DEMANDED

PLAINTIFF'S ORIGINAL COMPLAINT

Plaintiff, TOMMIE L. GOMEZ, on behalf of herself, by and through her undersigned attorney, sues Defendant Merck & Company, Inc., and allege as follows:

I. JURISDICTION AND VENUE

1. This Court has jurisdiction pursuant to 28 U.S.C. § 1332, as complete diversity exists between Plaintiff and the Defendant. Plaintiff is a resident of Texas, and Defendant is incorporated and has its primary place of business in the State of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds \$75,000.
2. Venue is proper within this district and division pursuant to 28 U.S.C. § 1391, as a substantial number of the events, actions, or omissions giving rise to the Plaintiff's claims occurred in this district. At all times relevant to this matter, Defendant Merck conducted substantial business in this district.

II. PARTIES

3. Plaintiff Tommie L. Gomez was born June 8, 1951. At all relevant times, Plaintiff was a resident of San Angelo, Texas. Plaintiff used Fosamax from approximately

October 15, 2002 until she was diagnosed with Osteonecrosis of the Jaw in April 2006.

4. Defendant is a corporation organized and existing under the law of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's principal office is located at One Merck Drive, Whitehouse Station, New Jersey.
5. Defendant was at all relevant times authorized to conduct business in the State of Texas.
6. Defendant has regularly transacted business in the State of Texas and continues to do so.
7. At all relevant times, Defendant, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of Fosamax, a bisphosphonate drug used primarily to mitigate or reverse the effects of Osteoporosis, Osteopenia, and Paget's Disease.
8. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed Fosamax in the State of Texas.
9. Defendant derives substantial revenue from pharmaceutical products used or consumed in the State of Texas.
10. Defendant expected, or should have expected, that its business activities could or would have consequences within the State of Texas.
11. Plaintiff brings this action individually to recover damages, restitution, refund and/or for equitable, injunctive and declaratory relief against Defendants.

12. Defendant placed Fosamax into the stream of worldwide commerce and interstate commerce in the United States. It did so without adequate testing and with no warning that the drug carried with it a risk of causing Osteonecrosis of the Jaw.
13. Plaintiff needs continued medical monitoring to prevent or mitigate the future onset of Osteonecrosis of the Jaw or treat Osteonecrosis of the Jaw which has already manifested.

III.SUMMARY OF THE CASE

14. Defendant, either directly or through its agents, apparent agents, servants or employees designated, manufactured, marketed, advertised, distributed and sold Fosamax for the treatment of Osteoporosis, Paget's Disease, and other uses.
15. As a result of the defective nature of Fosamax, persons who were prescribed and ingested Fosamax, including Plaintiff Tommie L. Gomez, have suffered and may continue to Fosamax severe and permanent personal injuries, including Osteonecrosis of the Jaw.
16. Defendant concealed and continues to conceal its knowledge of Fosamax's unreasonably dangerous risks from Plaintiff Tommie L. Gomez, other consumers, and the medical community.
17. Defendant failed to conduct adequate and sufficient post-marketing surveillance of Fosamax after it began marketing, advertising, distributing, and selling the drug.
18. As a result of Defendant's actions and inaction, Plaintiff Tommie L. Gomez was injured due to her ingestion of Fosamax, which has caused and will continue to cause Plaintiff's various injuries and damages. Plaintiff accordingly seeks compensatory damages.

IV. FACTUAL BACKGROUND

19. At all relevant times, Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling Fosamax.
20. In September 1995, the United States Food and Drug Administration (“FDA”) approved Merck’s compound Alendronate for various uses, including the treatment of Osteoporosis and Paget’s Disease. Alendronate is marketed by Defendant Merck as Fosamax.
21. Fosamax falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as Osteoporosis and Paget’s disease. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy, but are not indicated for use in non-cancerous conditions such as Osteoporosis.
22. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (Fosamax). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate contains a nitrogen atom. The Physicians Desk Reference (“PDR”) for Fosamax confirms that the molecule contains a nitrogen atom.
23. Throughout the 1990s and 2000s, medial articles and studies appeared reporting the frequent and common occurrence of Osteonecrosis of the Jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal

tract, Merck knew or should have known that Fosamax, as a nitrogenous bisphosphonate, shared a similar adverse event profiles to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

24. Merck knew or should have known that bisphosphonates, including Fosamax, inhibit endothelial cell function. Similarly, Merck knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patient's mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.
25. Merck also knew or should have known that these actors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turning into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).
26. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on Fosamax.
27. Once the Osteonecrosis beings and becomes symptomatic, it is very difficult to treat and typically is not reversible.
28. Shortly after the Defendant began selling Fosamax, reports of Osteonecrosis of the Jaw and other dental complications among users began surfacing, indicating that Fosamax shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study of the risk of Osteonecrosis of the Jaw relative to Fosamax. Rather than evaluating and verifying the safety of Fosamax with respect to Osteonecrosis of the Jaw, Defendant proposed

further uses of Fosamax, such as Fosamax-D, and sought to extend the exclusivity period of Fosamax through 2018.

29. Osteonecrosis of the Jaw is a serious medical event and can result in severe disability and death.
30. Since Fosamax was released, the FDA has received a significant number of reports of Osteonecrosis of the Jaw among users of Fosamax.
31. On August 25, 2004, the United States Food & Drug Administration (“FDA”) posted its ODS Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (Fosamax). This was an epidemiologic review of the FDA adverse events database conducted by the FDA’s Division of Drug Risk Evaluation.
32. As a result of the FDA review, the FDA observed that the risk of Osteonecrosis of the Jaw was not confined to bisphosphonates used for chemotherapy. The FDA’s review indicated that the Osteonecrosis of the Jaw was a class effect which specifically extended to the oral bisphosphonate, Fosamax.
33. As a result, the FDA recommended and stated that the labeling for Fosamax should be amended by Defendant to specifically warn about the risk of Osteonecrosis of the Jaw. Defendant has refused to accede to the FDA’s request and does not warn of the risk of Osteonecrosis of the Jaw in its Fosamax labeling.
34. Rather than warn patients, and despite knowledge known by Defendant about increased risk of Osteonecrosis of the Jaw on patients using Fosamax, Defendant continues to defend Fosamax, mislead physicians and the public and minimize unfavorable findings.

35. Fosamax is one of Defendant's top selling drugs, averaging more than \$3 billion a year in sales.
36. Consumers, including Plaintiff Tommie L. Gomez, who have used Fosamax for treatment of Osteoporosis, have several alternative safer products available to treat the conditions.
37. Defendant knew of the significant risk of dental and oral complications caused by ingestion of Fosamax, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff Tammie L. Gomez, or the medical community, of such risks.
38. As a direct result, Plaintiff Tammie L. Gomez was prescribed Fosamax and has been permanently and severely injured, having suffered serious consequences from the ingestion of Fosamax. Plaintiff Tammie L. Gomez requires and will in the future require ongoing medical care and treatment.
39. Plaintiff Tammie L. Gomez has suffered from mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the use of Fosamax.
40. Plaintiff Tammie L. Gomez was prescribed and began taking Fosamax in October 2002.
41. Plaintiff used Fosamax as prescribed and in a foreseeable manner.
42. As a direct and proximate cause result of using Fosamax, Plaintiff suffered severe Osteonecrosis of the Jaw.

43. Plaintiff, as a direct and proximate result of using Fosamax, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.
44. Plaintiff used Fosamax which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.
45. Plaintiff would not have used Fosamax had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of Osteonecrosis of the Jaw and would have been able to avoid the clinical manifestations of symptoms as they currently exist.
46. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking Fosamax. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.
47. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

V. COUNTS

COUNT 1: NEGLIGENCE

48. Plaintiff restates the allegations set forth above as if fully rewritten herein.

49. Defendant owed Plaintiff, Tommie L. Gomez, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling Fosamax.
50. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:
 - a. failing to properly and thoroughly test Fosamax before releasing the rug to the market;
 - b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of Fosamax;
 - c. failing to conduct sufficient post-market testing and surveillance of Fosamax;
 - d. Designing, manufacturing, marketing, advertising, distributing, and selling Fosamax to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Fosamax and without proper instructions to avoid the harm which could foreseeable occur as a result of using the drug;
 - e. failing to exercise due care when advertising and promoting Fosamax; and
 - f. negligently continuing to manufacturer, market, advertise, and distribute Fosamax after Defendant knew or should have known of its adverse effects.
51. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff Tommie L. Gomez sustained Osteonecrosis of the Jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the

enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering loss of wages and wage-earning capacity.

52. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT II: STRICT LIABILITY

53. Plaintiff restates the allegations set forth above as if fully rewritten herein.
54. Defendant manufactured, sold, distributed, marketed, and/or supplied Fosamax n a defective and unreasonably dangerous condition to consumers, including Plaintiff Tommie L. Gomez.
55. Defendant designed, manufactured, sold, distributed, supplied, marketed and/or promoted Fosamax, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.
56. Plaintiff used Fosamax as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.

57. Fosamax failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.
58. Fosamax was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.
59. Fosamax was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.
60. Fosamax was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of Osteonecrosis of the Jaw.
61. Although Defendant knew or should have known of the defective nature of Fosamax, it continued to design, manufacture, market, and sell Fosamax so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by Fosamax.
62. Plaintiff could not, through the exercise of reasonable care, have discovered Fosamax's defects or perceived the dangers posed by the drug.
63. As a direct and proximate consequence of Defendant's conduct, Plaintiff Tommie L. Gomez sustained Osteonecrosis of the Jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to

suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering loss of wages and wage-earning capacity.

64. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT III: BREACH OF EXPRESS WARRANTY

65. Plaintiff restates the allegations set forth above as if fully rewritten herein.
66. Defendant expressly represented to Plaintiff Tommie L. Gomez and other consumers and the medical community that Fosamax was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.
67. Fosamax does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.
68. At all relevant times, Fosamax did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.
69. Plaintiff Tommie L. Gomez, other consumers, and the medical community relied upon Defendant's express warranties.

70. As a direct and proximate consequence of Defendant's conduct, Plaintiff Tommie L. Gomez sustained Osteonecrosis of the Jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering loss of wages and wage-earning capacity.
71. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT IV: BREACH OF IMPLIED WARRANTY

72. Plaintiff restates the allegations set forth as if fully rewritten herein.
73. Defendant manufactured, distributed, advertised, promoted, and sold Fosamax.
74. At all relevant times Defendant knew of the use for which Fosamax was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.
75. Defendant was aware that consumers, including Plaintiff Tommie L. Gomez, would use Fosamax for treatment of Osteoporosis and for other purposes.

76. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell Fosamax only if it was indeed of merchantable quality and safe and fit for its intended use.
77. Defendant breached its implied warranty to consumers, including Plaintiff; Fosamax was not of merchantable quality or safe and fit for intended use.
78. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendant's implied warranty for Fosamax.
79. Fosamax reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.
80. As a direct and proximate consequence of Defendant's conduct, Plaintiff Tommie L. Gomez sustained Osteonecrosis of the Jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering loss of wages and wage-earning capacity.
81. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT V: FRAUDULENT MISREPRESENTATION

82. Plaintiff restates the allegations set forth above as if fully rewritten herein.
83. Defendant made fraudulent misrepresentations with respect to Fosamax in the following particulars:
 - a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Fosamax had been tested and found to be safe and effective for the treatment of pain and inflammation; and
 - b. Defendant represented that Fosamax was safer than other alternative medications.
84. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of Fosamax to consumers, including Plaintiff, and the medical community.
85. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.
86. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of Fosamax.
87. Plaintiff's doctors and other relied upon the representations.
88. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

89. As a direct and proximate consequence of Defendant's conduct, Plaintiff Tommie L. Gomez sustained Osteonecrosis of the Jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering loss of wages and wage-earning capacity.
90. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT VI: FRAUDULENT CONCEALMENT

91. Plaintiff restates the allegations set forth above as if fully rewritten herein.
92. Defendant fraudulent concealed information with respect to Fosamax in the following particulars:
- a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Fosamax was safe and fraudulently withheld and concealed information about the substantial risk of using Fosamax; and

- b. Defendant represented that Fosamax was safer than other alternative medications and fraudulently concealed information which demonstrated that Fosamax was not safer than alternatives available on the market.
93. Defendant had sole access to material facts concerning the dangers and unreasonable risks of Fosamax.
94. The concealment of information by Defendant about the risks of Fosamax was intentional, and the representations made by Defendant were known by Defendant to be false.
95. The concealment of information and the misrepresentation about Fosamax were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.
96. Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks of Fosamax which Defendant concealed from Plaintiff's doctors and Plaintiff.
97. As a direct and proximate consequence of Defendant's conduct, Plaintiff Tommie L. Gomez sustained Osteonecrosis of the Jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring,

treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering loss of wages and wage-earning capacity.

98. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT VII: EQUITABLE RELIEF
MEDICAL MONITORING PROGRAM AND PROPER LABELING

99. Plaintiff restates the allegations set forth above as if fully rewritten herein.
100. As a direct and proximate result of Defendant's acts, Plaintiff face an increased susceptibility to injuries as described herein. The irreparable threat to their health can only be mitigated by the creation of a medical monitoring fund to provide for a medical monitoring program, including: notifying Plaintiff of the defects and the potential medical harm; funding of a program for the surgical treatment of Osteonecrosis of the Jaw; funding a study of the long term effects of Fosamax within the body of Plaintiff; gathering and forwarding to treating physicians information relating to the diagnosis and treatment of injuries which may result from the product; aiding in the early diagnosis and treatment of resulting injuries; and providing funding for diagnosis and preventable medical treatment, particularly dental and oral monitoring.
101. Plaintiff has no adequate remedy in law in that monetary damages alone do not compensate for the insidious and continuing nature of the harm to her, and only a medical monitoring program which notified Plaintiff and aids in correcting the problems can prevent the greater harms which may not occur immediately and which

may be preventable, if proper research is conducted and the health risks are diagnoses and treated before they occur or become worse.

102. Plaintiff has suffered irreparable harm as alleged herein and, in the absence of equitable relief, Plaintiff will suffer further irreparable harm such as death and severe and debilitating injuries from continued retention of the defective drug. Without a medical monitoring program, Plaintiff might not receive prompt medical care which could prolong their productive lives, increase prospects for improvement and minimize disability.
103. Additionally, Defendant has refused to abide by the FDA's request to amend its product labeling information to warn physicians and patients about the risk of Osteonecrosis of the Jaw. Because of this failure, prescribing physicians are unable to warn patients to be aware of precursors symptoms which, if properly observed and reported to the physician, could result in discontinuation of Fosamax therapy and the prevention or mitigation of the Osteonecrosis of the Jaw.
104. This Court should use its equitable powers, in the interest of public safety and in order to make sure that prescribing physicians have a complete understanding of the risks associated with Fosamax, to require Defendant to change its label in a form approvable by the FDA to adequately warn physicians and Fosamax patients about the risk of Osteonecrosis of the Jaw and steps which can be taken to prevent or mitigate its occurrence.

COUNT VIII: PUNITIVE DAMAGES

105. Plaintiff restates the allegations set forth above as if fully rewritten herein.

106. Defendant has repeatedly engaged in a pattern of conduct of deliberately avoiding FDA recommendations as which warnings relating to public hazards should be warned about.
107. For instance, in March 2000, Defendant completed a study called VIGOR (Vioxx Gastrointestinal Outcomes Research) relating to its prescription cox-2 inhibitor, Vioxx. The VIGOR study showed that Vioxx patients had more than double the rate of serious cardiovascular problems than those on Naproxen, an older non-steroidal anti-inflammatory drug.
108. In September 2001, the FDA warned Defendant to stop misleading doctors about Vioxx's effect on the cardiovascular system. Defendant Merck was admonished to stop minimizing the risks of the drug in its marketing. Despite that, Defendant refused to adequately warn physicians and patients about the risk of heart attacks and Vioxx.
109. On August 25, 2004, a representative from the FDA presented results of a database analysis of 1.4 million patients. The analysis demonstrated that Vioxx users were more likely to suffer a heart attack or sudden cardiac death than those taking Celebrex or older non-steroidal drugs. The FDA representative concluded that Vioxx was linked to more than 27,000 heart attacks or sudden cardiac deaths nationwide from the time it came on the market in 1999 through 2003.
110. On August 26, 2004, Defendant released a press statement which refuted the FDA analysis and restated Defendant's support for the cardiovascular safety of Vioxx.
111. On September 30, 2004, Defendant recalled Vioxx from the market, after having to halt the APPROVe study (Adenomatous Polyp Prevention on Vioxx). The study was

underway to evaluate the use of Vioxx for recurrent colon polyps. The researchers found an alarming number of cardiovascular events among the drug's users in the APPROVe study.

112. At that same time, Defendant was aware that the FDA, as of August 24, 2004, was advising Defendant to warn about the risk of Osteonecrosis of the Jaw for its Fosamax patients. Because Defendant knew that its blockbuster drug Vioxx was about to be pulled from the market, placing more importance on the \$3 billion+ annual sales of Fosamax, Defendant deliberately chose to not amend its packaging of Fosamax to include the risk of Osteonecrosis of the Jaw, fearing that such a warning would result in reduced revenues for its second largest income producer, Fosamax.
113. Defendant's acts were willful and malicious in that Defendant's conduct was carried on with a conscious disregard for the safety and rights of Plaintiff. Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendant in an amount appropriate to punish Defendant, and deter similar conduct in the future.

WHEREFORE, Plaintiff, individually, prays for judgment against Defendant, as follows:

1. For general damages in an amount to be proved at the time of trial;
2. For special damages in an amount to be proved at the time of trial;
3. For exemplary and punitive damages in an amount to be proved at the time of trial and sufficient to punish Defendant or to deter Defendant and others from repeating the injurious conduct alleged herein;
4. For pre-judgment and post-judgment interest on the above general and special damages;


5. For costs of this suit and attorneys' fees; and
6. All other relief that Plaintiff may be entitled to at equity or at law, including but not limited to the funding of a medical monitoring program and compelling Defendant to adequately warn about the risk of Osteonecrosis of the Jaw and Fosamax.

COUNT IX: DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

DATED this 4th day of April, 2008.

WATTS LAW FIRM, LLP



AUSTIN W. ANDERSON
SBN: 24045189
555 North Carancahua
Tower II, 14th Floor
Corpus Christi, Texas 78478
(361) 887-0500 [telephone]
(361) 887-0055 [facsimile]

Attorney for Plaintiff

CIVIL COVER SHEET **6 08 CV - 017 - C**

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Tommie L. Gomez

DEFENDANTS

Merck & Co., Inc.

(b) County of Residence of First Listed Plaintiff Tom Green

(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant New Jersey

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)

Watts Law Firm, LLP, 555 N. Carancahua, Tower II, 14th Floor,
Corpus Christi, TX 78478

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- (For Diversity Cases Only)
- | | | | | | |
|---|---|--------------------------------|---|--------------------------------|---------------------------------------|
| Citizen of This State | PTF <input checked="" type="checkbox"/> 1 | DEF <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | PTF <input type="checkbox"/> 4 | DEF <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS - Third Party 26 USC 7609
				<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes

V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☒ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify)
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

28 USC 1391 & USC 1332

Brief description of cause:

Pharmaceutical Product Liability

VII. REQUESTED IN COMPLAINT:☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND:

☒ Yes ☐ No**VIII. RELATED CASE(S) PENDING OR CLOSED**

(See instructions):

JUDGE

DOCKET NUMBER

DATE

04/04/2008

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # 5A000518 AMOUNT 350.00

APPLYING IFP

JUDGE

MAG. JUDGE

UNITED STATES DISTRICT COURT

Northern District of Texas

District of

San Angelo

Tommie L. Gomez, Individually,

SUMMONS IN A CIVIL ACTION

V.
Merck & Co., Inc.

CASE NUMBER:

6 08 CV - 017 - C

TO: (Name and address of Defendant)

Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Austin W. Anderson
Watts Law Firm, LLP
555 North Carancahua
Tower II, 14th Floor
Corpus Christi, TX 78478

an answer to the complaint which is served on you with this summons, within 20 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

CLERK OF COURT

CLERK

(B) DEPUTY CLERK

DATE

April 8, 2008

AO 440 (Rev. 8/01) Summons in a Civil Action

RETURN OF SERVICE		
Service of the Summons and complaint was made by me ⁽¹⁾	DATE	
NAME OF SERVER (<i>PRINT</i>)	TITLE	
<i>Check one box below to indicate appropriate method of service</i>		
<div style="margin-bottom: 10px;"> <input type="checkbox"/> Served personally upon the defendant. Place where served: </div> <div style="margin-bottom: 10px;"> <input type="checkbox"/> Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein. Name of person with whom the summons and complaint were left: </div> <div style="margin-bottom: 10px;"> <input type="checkbox"/> Returned unexecuted: </div> <div> <input type="checkbox"/> Other (specify): </div>		
STATEMENT OF SERVICE FEES		
TRAVEL	SERVICES	TOTAL \$0.00
DECLARATION OF SERVER		
<p>I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> Executed on _____ <div style="text-align: center; margin-top: 5px;">Date</div> </div> <div style="width: 60%;"> _____ <div style="text-align: center; margin-top: 5px;">Signature of Server</div> </div> </div> <div style="text-align: center; margin-top: 20px;"> _____ <div style="margin-top: 5px;">Address of Server</div> </div>		

(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS**

TO: All Attorneys of Record in Cases Assigned to the Docket of Judge Sam R. Cummings, United States District Judge, Northern District of Texas

**STANDING ORDER¹ DESIGNATING CASE FOR ENROLLMENT
IN THE ELECTRONIC CASE FILES “ECF” SYSTEM**

The court has determined that this case will be enrolled in the Electronic Case Files (“ECF”) system as an ECF case. Therefore, it is **ORDERED** that all counsel of record *must register* as an ECF user **within ten days of the date of notice of this order**, if they have not already done so and if they choose to file documents electronically. Counsel may file paper documents if they choose not to file electronically. Only licensed attorneys may submit documents for electronic filing, so a *pro se* party (including a prisoner) will not be permitted to register as an ECF user or submit documents electronically. To register, counsel must:

1. Review Miscellaneous Order Number 61;
2. Review the ECF Administrative Procedures Manual;
3. Complete the online attorney tutorial for ECF training;
4. Review the ECF User Guide;
5. Complete the ECF Attorney/User Registration Form and forward it to the Clerk’s Office; and

¹Upon opening a new case, the clerk shall enter this Standing Order. If the plaintiff or petitioner in a civil action is proceeding *pro se*, the clerk shall not distribute this order unless there is an order for process to issue. If process is ordered to issue, the clerk is directed at that time to send a copy of this order to the defendant or respondent with the service of the summons or show cause order.

6. Ensure that any attorney granted *Pro Hac Vice* admission as co-counsel in this case **also registers as an ECF user.**

**DUTY OF INITIATING PARTY
TO SERVE ECF DESIGNATION ORDER UPON OPPOSING PARTY**

It is further **ORDERED** that in a civil ECF case the party initiating the action in this court shall serve a copy of this order on the opposing party(ies) with service of process or within five days of receipt of this order, whichever is later. If an additional party is joined in a civil ECF case at a later date, the party joining the additional party is **ORDERED** to serve a copy of this order on the additional party within five days of when the additional party is joined.

In a criminal ECF case it is **ORDERED** that the government serve a copy of this order on defendant's counsel when defendant's counsel makes an appearance in the case on behalf of the defendant.

ELECTRONIC CASE FILES REQUIREMENTS


If an attorney chooses to file electronically, counsel must observe the following directives:

1. **ECF DESIGNATION:** ALL documents submitted for filing must include the "ECF" designation in the caption of the case directly beneath the case number.
2. **GOVERNING DOCUMENTS:** The case will be governed by Miscellaneous Order Number 61, the ECF Administrative Procedures Manual, and the ECF User Guide.

3. **SERVICE OF DOCUMENTS UPON NON-ECF USERS:** Service of documents upon non-ECF users (including *pro se* litigants) must be effected on paper in a manner authorized by Federal Rule of Civil Procedure 5.
4. **PROPOSED ORDERS:** A proposed order shall be submitted with **EVERY** motion via e-mail as instructed under the ECF system's "Proposed Orders" event.
5. **AMENDED PLEADINGS:** A party who moves for leave to file an amended pleading must attach the proposed amended pleading as an exhibit to the motion for leave. If the motion for leave is granted, the moving party shall submit the amended pleading for filing within three days after leave is **granted**, unless otherwise ordered by the court.
6. **PRIVACY POLICY:** Counsel must ensure that all documents filed with the court strictly comply with the privacy policy of the U.S. District Court for the Northern District of Texas. The privacy policy restricts the use and manner of use of certain types of information, including: social security numbers, tax identification numbers, minors' names, birth dates, financial account numbers, medical records, employment histories, proprietary or trade secret information, crime victim information, national security information, sensitive security information as described in 49 U.S.C. § 114(s), and information regarding an individual's cooperation with the government. The complete policy may be found at <http://www.txnd.uscourts.gov/pdf/TXNprivnot.pdf>.

7. **QUESTIONS:** ECF questions should be directed to the Clerk's Office for the division where the case is pending or to the ECF Help Desk at (866)243-2866.²

SO ORDERED this 1st day of September, 2006.



SAM R. CUMMINGS
UNITED STATES DISTRICT COURT

²Each attorney who is registered as an ECF user is able to submit a document for filing with the court over the Internet at any time from any location. For more information on the benefits of using the ECF system, visit the U.S. Courts' Internet website at <http://www.uscourts.gov/cmecf/cmecf.html> and click on "Video: The Attorneys' Perspective." Information regarding the operation of the ECF system in the Northern District of Texas is available on the website for the U.S. Courts for the Northern District of Texas at <http://www.txnd.uscourts.gov/filing/ecf.html>.

Austin W. Anderson
WATTS LAW FIRM, L.L.P.
555 North Carancahua, 14th Floor
Corpus Christi, Texas 78478
Telephone: (361) 887-0500
Facsimile: (361) 887-0055
aanderson@wattslawfirm.com

Attorney for Plaintiff.

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
(SAN ANGELO DIVISION)**

TOMMIE L. GOMEZ,

Plaintiff,

v.

MERCK & CO., INC.

Defendant.

Case No. 6-08-CV-017-C

PLAINTIFF'S CERTIFICATE OF INTERESTED PARTIES

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, TOMMIE L. GOMEZ, Plaintiff in the above-styled and numbered cause, and pursuant to the Federal Rules of Civil Procedure, makes and files this, her Certificate of Interested Parties, and would respectfully show the Court as follows:

Plaintiff files this Certificate of Interested Parties, as follows:

1. Tommie L. Gomez, Plaintiff

Plaintiff can be reached through counsel of record:

Austin W. Anderson
Watts Law Firm, L.L.P.
Tower II Building, 14th Floor
555 North Carancahua
Corpus Christi, Texas 78478
(361) 887-0500 [Telephone]
(361) 887-0055 [Facsimile]

2. Watts Law Firm, L.L.P.
Mikal C. Watts
Anthony E. Pletcher
Austin W. Anderson
Tower II Building, 14th Floor
555 North Carancahua
Corpus Christi, Texas 78478
(361) 887-0500 [Telephone]
(361) 887-0055 [Facsimile]
3. Merck & Co., Inc, Defendant
One Merck Drive
Whitehouse Station, New Jersey 08889
(973) 360-1100 [Telephone]
(973) 360-9831 [Facsimile]

Respectfully submitted,

By: /s/ Austin W. Anderson
Austin W. Anderson
State Bar No. 24045189
Mikal C. Watts
State Bar No. 20981820
Anthony E. Pletcher
State Bar No. 16069800
Federal ID No. 2842
WATTS LAW FIRM, L.L.P.
Tower II Building, 14th Floor
555 North Carancahua
Corpus Christi, Texas 78478
(361) 887-0500 [Telephone]
(361) 887-0055 [Facsimile]

COUNSEL FOR PLAINTIFF

Dated: April 11, 2008

CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing instrument was forwarded to all counsel of record by the method of service indicated below, on this, the 11th day of April, 2008.

/s/ Austin W. Anderson
Austin W. Anderson

Via Certified Mail

Merck & Co., Inc, Defendant
One Merck Drive
Whitehouse Station, New Jersey 08889
(973) 360-1100 [Telephone]
(973) 360-9831 [Facsimile]

UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF TEXAS
SAN ANGELO DIVISION

TOMMIE L. GOMEZ,	§	
	§	
Plaintiff,	§	
	§	
v.	§	Civil Action No. 6-08-CV-017-C
	§	
MERCK & CO., INC.,	§	JURY TRIAL DEMANDED
	§	
Defendant.	§	

ANSWER AND AFFIRMATIVE DEFENSES OF MERCK & CO., INC.

Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

I. JURISDICTION AND VENUE

1. The allegations of the first sentence of Paragraph 1 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of the first sentence of Paragraph 1. As to the allegations of the second sentence of Paragraph 1, Merck is without knowledge or information sufficient to form a belief as to these allegations, except that Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey. Merck is without knowledge as to the allegations in the third sentence of Paragraph 1, but for jurisdictional purposes only, admits that the Plaintiff seeks in excess of \$75,000.

2. The allegations of the first sentence of Paragraph 2 are conclusions of law to which no response is required. To the extent a response is required, Merck denies the allegations of said sentence. As to the allegations of the second sentence of Paragraph 2, Merck is without

knowledge as to what is meant by the phrase “substantial business,” so the allegations of said sentence are denied.

II. PARTIES

3. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of the first and second sentences of Paragraph 3. Merck denies each and every allegation of the third sentence of Paragraph 3, except Merck states that it is without knowledge as to whether and when Plaintiff used FOSAMAX®.

4. Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in Whitehouse Station, New Jersey. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 4.

5. Merck admits that it is registered to do business in the State of Texas.

6. Merck is without knowledge as to what is meant by the phrase “regularly transacted,” so the allegations in Paragraph 6 are denied.

7. Merck denies each and every allegation of Paragraph 7, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 7 inconsistent with that prescribing information and respectfully refers the Court to the Physician’s Desk Reference (“PDR”) for FOSAMAX® for its actual language and full text.

8. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 8 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for

FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 8.

9. Merck is without knowledge as to what is meant by the phrase “substantial revenue,” so the allegations in Paragraph 9 are denied.

10. Merck is without knowledge as to what is meant by “consequences,” so the allegations in Paragraph 10 are denied.

11. Merck admits that Plaintiff purports to bring an action for damages and other relief, but denies that there is any legal or factual basis for same.

12. Merck denies each and every allegation of Paragraph 12, except that it admits that Merck distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

13. Merck denies each and every allegation of Paragraph 13.

III. SUMMARY OF THE CASE

14. Merck denies each and every allegation of Paragraph 14, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

15. Merck denies each and every allegation of Paragraph 15.

16. Merck denies each and every allegation of Paragraph 16.

17. Merck denies each and every allegation of Paragraph 17.

18. Merck denies each and every allegation of Paragraph 18.

IV. FACTUAL BACKGROUND

19. Merck denies each and every allegation of Paragraph 19, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

20. Merck denies each and every allegation of Paragraph 20, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 20 inconsistent with that prescribing information.

21. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 21 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 21 with respect to Aredia and Zometa inconsistent with that prescribing information.

22. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 22 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in Paragraph 22 with respect to Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23.
24. Merck denies each and every allegation of Paragraph 24.
25. Merck denies each and every allegation of Paragraph 25.
26. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 26.
27. Merck denies each and every allegation of Paragraph 27.
28. Merck denies each and every allegation of Paragraph 28.
29. Merck denies each and every allegation of Paragraph 29.
30. Merck denies each and every allegation of Paragraph 30.
31. Merck denies each and every allegation of Paragraph 31, except that Merck admits that the FDA drafted an “ODS Postmarketing Safety Review,” but respectfully refers the Court to said document for its actual language and full text.
32. Merck denies each and every allegation of Paragraph 32.
33. Merck denies each and every allegation of Paragraph 33.
34. Merck denies each and every allegation of Paragraph 34.
35. Merck denies each and every allegation of Paragraph 35, except that Merck admits that Fosamax product sales in 2007 amounted to approximately \$3.05 billion.
36. Merck is without knowledge as to whether Plaintiff used FOSAMAX®. Merck denies the remaining allegations in Paragraph 36.
37. Merck denies each and every allegation of Paragraph 37.
38. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX®. Merck denies the remaining allegations in Paragraph 38.
39. Merck denies each and every allegation of Paragraph 39.

40. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 40.

41. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

44. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 44.

45. Merck denies each and every allegation of Paragraph 45.

46. Merck denies each and every allegation of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47.

V. COUNTS

COUNT I: NEGLIGENCE

48. Merck repleads its answers to Paragraphs 1 through and including 47, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

49. The allegations in Paragraph 49 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

50. Merck denies each and every allegation of Paragraph 50, including each and every allegation contained in subparts (a) through (f).

51. Merck denies each and every allegation of Paragraph 51.

52. Merck denies each and every allegation of Paragraph 52.

COUNT II: STRICT LIABILITY

53. Merck repleads its answers to Paragraphs 1 through and including 52, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

54. Merck denies each and every allegation of Paragraph 54, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

55. Merck denies each and every allegation of Paragraph 55, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.

56. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

60. Merck denies each and every allegation of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

64. Merck denies each and every allegation of Paragraph 64.

COUNT III: BREACH OF EXPRESS WARRANTY

65. Merck repleads its answers to Paragraphs 1 through and including 64, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

66. Merck denies each and every allegation of Paragraph 66, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

67. Merck denies each and every allegation of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

69. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 69.

70. Merck denies each and every allegation of Paragraph 70.

71. Merck denies each and every allegation of Paragraph 71.

COUNT IV: BREACH OF IMPLIED WARRANTY

72. Merck repleads its answers to Paragraphs 1 through and including 71, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

73. Merck denies each and every allegation of Paragraph 73, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

74. Merck denies each and every allegation of Paragraph 74, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained

therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

75. Merck denies each and every allegation of Paragraph 75.

76. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 76.

77. Merck denies each and every allegation of Paragraph 77.

78. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 78.

79. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 79.

80. Merck denies each and every allegation of Paragraph 80.

81. Merck denies each and every allegation of Paragraph 81.

COUNT V: FRAUDULENT MISREPRESENTATION

82. Merck repleads its answers to Paragraphs 1 through and including 81, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

83. Merck denies each and every allegation of Paragraph 83, including each and every allegation contained in subparts (a) through (b).

84. Merck denies each and every allegation of Paragraph 84.

85. Merck denies each and every allegation of Paragraph 85.

86. Merck denies each and every allegation of Paragraph 86.

87. Merck denies each and every allegation of Paragraph 87.

88. Merck denies each and every allegation of Paragraph 88.

89. Merck denies each and every allegation of Paragraph 89.

90. Merck denies each and every allegation of Paragraph 90.

COUNT VI: FRAUDULENT CONCEALMENT

91. Merck repleads its answers to Paragraphs 1 through and including 90, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

92. Merck denies each and every allegation of Paragraph 92, including each and every allegation contained in subparts (a) through (b).

93. Merck denies each and every allegation of Paragraph 93.

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97.

98. Merck denies each and every allegation of Paragraph 98.

COUNT VII: EQUITABLE RELIEF
MEDICAL MONITORING PROGRAM AND PROPER LABELING

99. Merck repleads its answers to Paragraphs 1 through and including 98, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

100. Merck denies each and every allegation of Paragraph 100.

101. Merck denies each and every allegation of Paragraph 101.

102. Merck denies each and every allegation of Paragraph 102.

103. Merck denies each and every allegation of Paragraph 103.

104. Merck denies each and every allegation of Paragraph 104 and denies that Plaintiff is entitled to any of the relief requested.

COUNT VIII: PUNITIVE DAMAGES

105. Merck repleads its answers to Paragraphs 1 through and including 104 and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

106. Merck denies each and every allegation of Paragraph 106

107. Merck denies each and every allegation of Paragraph 107, except that it admits that Merck scientists participated in the VIGOR study involving Vioxx®, published in the New England Journal of Medicine, and respectfully refers the Court to the referenced study for its actual conclusions and full text.

108. Merck denies each and every allegation of Paragraph 108, except that it admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.

109. Merck denies each and every allegation of Paragraph 109.

110. Merck denies each and every allegation of Paragraph 110, except that it admits that on August 26, 2004, Merck issued a press release regarding the conclusions of a study presented at the 20th International Conference on Pharmacoepidemiology & Therapeutic Risk Management and respectfully refers the Court to that press release for its actual language and full text.

111. Merck denies each and every allegation of Paragraph 111, except that it admits that the referenced study exists and respectfully refers the Court to said study for its actual language and full text. Merck further admits that on September 30, 2004, Merck announced that

in a prospective, randomized, placebo-controlled clinical trial there was an increased relative risk for confirmed cardiovascular events beginning after 18 months of treatment in the patients taking Vioxx compared with those taking placebo, and that, given the availability of alternative therapies and questions raised by the data from that trial, Merck concluded that a voluntary withdrawal of Vioxx best served the interests of patients.

112. Merck denies each and every allegation of Paragraph 112.

113. Merck denies each and every allegation of Paragraph 113.

Merck denies that Plaintiff is entitled to any of the relief requested in her Wherefore clause.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiffs directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the complaint. Merck anticipates more specific information regarding the identity and potential liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned.

EIGHTH AFFIRMATIVE DEFENSE

The injuries and damages, if any, sustained by the Plaintiffs resulted in whole or in part from their own comparative negligence and any damages recovered should be reduced accordingly.

NINTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the complaint, such injuries or losses were only sustained after Plaintiffs knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or another manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiffs' misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the complaint, such injuries or losses resulted from Plaintiffs' pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused the injuries asserted in the complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recovery for strict liability because Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiffs' claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and Texas Constitutions.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action processed and distributed by Merck in any state in the United States was processed and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a

duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs have not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs have not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

FORTIETH AFFIRMATIVE DEFENSE

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiffs for any amounts received from collateral sources.

FORTY-FIRST AFFIRMATIVE DEFENSE

To the extent that Plaintiffs asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under

the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims of fraud are not pleaded with the required particularity.

FORTY-THIRD AFFIRMATIVE DEFENSE

If Plaintiffs sustained the injuries and damages alleged in the Complaint, such injuries resulted, in whole or in part, from the culpable conduct and negligence of Plaintiffs and/or of third parties, not from any negligence or breach of duty by Merck. If judgment is rendered in Plaintiffs' favor, the amount of such judgment must be reduced pursuant to the Proportionate Responsibility Statute § 33.001, et seq. of the Texas Civil Practice & Remedies Code.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Merck is unaware at this time of any settlements by any alleged joint tortfeasor. In the event any settlement is or has been made by any alleged joint tortfeasor, however, then Merck is entitled to a full credit, offset, pro rata reduction, or percentage reduction, based on the percentage of fault attributable to each settling party, person, or other entity herein, and Merck makes known to the other parties and to the court that it will avail itself of its rights under §§ 33.012 et seq. of the Texas Civil Practice & Remedies Code.

FORTY-FIFTH AFFIRMATIVE DEFENSE

Merck fully asserts § 82.001 and § 82.007 of the Texas Civil Practice and Remedies Code and states that all of Plaintiffs' claims are barred under those sections.

FORTY-SIXTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims of fraud are barred by reason of Plaintiffs' failure to allege the circumstances constituting fraud with particularity, as required under both state and federal rules.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs fail to state a claim upon which relief can be granted for medical monitoring or compensation for medical monitoring.

FORTY-NINTH AFFIRMATIVE DEFENSE

Any claims for exemplary damages are limited by Section 41.008 of the Texas Civil Practice and Remedies Code to two times the amount of actual damages or \$200,000, whichever is greater. Merck asserts all other defenses and limitations on punitive damages contained in Chapter 41 of the Texas Civil Practice and Remedies Code.

FIFTIETH AFFIRMATIVE DEFENSE

Any claim for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law without proof of every element beyond a reasonable doubt would violate Merck's rights under Amendments IV, V, VI and XIV of the United States Constitution and under Sections 9, 10, 14 and 19 of Article I of the Texas Constitution.

FIFTY-FIRST AFFIRMATIVE DEFENSE

Unless Merck's liability for punitive damages and the appropriate amount of punitive damages are each required to be established by clear and convincing evidence under Texas law,

any awards of punitive damages would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

FIFTY-SECOND AFFIRMATIVE DEFENSE

Any claims for punitive damages against Merck cannot be sustained, because any award of punitive damages under Texas law without bifurcating the trial as to all punitive damages issues would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

FIFTY-EIGHTH AFFIRMATIVE DEFENSE

Any claim for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law subject to no pre-determined limit, either a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

FIFTY-NINTH AFFIRMATIVE DEFENSE

Any claims for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law by a jury that:

- (1) is not provided any standard of sufficient clarity for determining the appropriateness, or the appropriate size of any punitive damages award;
- (2) is not instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment;

(3) is not expressly prohibited from awarding punitive damages or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics;

(4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; or

(5) is not subject to judicial review on the basis of objective standards, would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

SIXTIETH AFFIRMATIVE DEFENSE

Any claims for punitive damages against Merck cannot be sustained, because an award of punitive damages under Texas law for the purpose of compensating Plaintiffs for elements of damages not otherwise recognized by Texas law would violate Merck's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by Section 19 of Article I of the Texas Constitution.

SIXTY-FIRST AFFIRMATIVE DEFENSE

Merck asserts that the determination of the amount of punitive damages, if any, should be bifurcated from the remaining issues pursuant to *Transportation Ins. Co. v. Moriel*, 879 S.W.2d 10 (Tex. 1994).

SIXTY-SECOND AFFIRMATIVE DEFENSE

The imposition of punitive damages violates the open courts provision of the Texas Constitution.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

Respectfully submitted,

BAKER BOTTS L.L.P.

/s/ Richard L. Josephson

Richard L. Josephson

Federal ID No. 04614

State Bar No. 11031500

910 Louisiana

Houston, Texas 77002

Telephone: (713) 229-1234

Telecopy: (713) 229-1522

ATTORNEY-IN-CHARGE FOR

MERCK & CO., INC.

OF COUNSEL:

W. Zachary Hughes

Federal I.D. No. 30097

State Bar No. 24032441

BAKER BOTTS L.L.P.

910 Louisiana

Houston, Texas 77002

Telephone: (713) 229-1234

Telecopy: (713) 229-1522

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was sent to all known counsel of record via the Court's electronic filing system, on this 30th day of April, 2008.

Austin W. Anderson
Watts Law Firm, LLP
555 North Carancahua
Tower II, 14th Floor
Corpus Christi, Texas 78478

/s/ W. Zachary Hughes
W. Zachary Hughes

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
SAN ANGELO DIVISION

TOMMIE L. GOMEZ,)	
)	
Plaintiff,)	
)	
v.)	
)	
MERCK & COMPANY, INC.,)	
)	Civil Action No. 6:08-CV-017-C
Defendant.)	ECF

ORDER

1. Pursuant to Rule 16(b), Fed. R. Civ. P., the Court establishes the following schedule for this case:

(a) All motions to join other parties and amend the pleadings must be filed by 3:00 p.m. on August 15, 2008.

(b) Unless otherwise identified pursuant to written discovery, experts must be disclosed pursuant to Fed. R. Civ. P. 26(a)(2) by 3:00 p.m. on November 14, 2008.

(c) All other pretrial motions, including motions for summary judgment, must be filed, and all discovery must be completed, by 3:00 p.m. on March 16, 2009.

Deadlines will “not be extended except upon good cause shown and by order of the Court.” *See Saavedra v. Murphy Oil U.S.A., Inc. v. Lou-Con, Inc.*, 930 F.2d 1104, 1107 (5th Cir. 1991).

2. Unless further ordered by the Court, the parties are not required to make initial disclosures under Rule 26(a)(1), Fed. R. Civ. P., and no conferences are required under Rule 26(f), Fed. R. Civ. P.

3. Counsel and unrepresented parties are expected to cooperate with each other in conducting discovery, clarifying the issues, and getting the case ready for trial. Specifically, counsel must strictly comply with the mandates set forth in *Dondi Properties Corp. v. Commerce Savs. and Loan Ass'n*, 121 F.R.D. 284 (N.D. Tex. 1988) (en banc) (per curiam).

4. Counsel are referred to the Standing Order Designating Case for Enrollment in the Electronic Case Files “ECF” System. Filing documents electronically is not mandatory, however. In all cases where electronic case filing is permitted, counsel may serve and respond to written discovery requests through electronic mail service. This discovery practice will be governed by Northern District of Texas Local Rules and this Court’s Local Rules regarding electronic case filing procedures.

5. Counsel and unrepresented parties are referred to the Local Rules of the Northern District of Texas, the Civil Justice Cost and Delay Reduction Plan of the Northern District of Texas, and the Local Rules of this Court.

6. All parties will be notified by separate order of the date of trial and the date for filing the proposed pretrial order.

SO ORDERED.

Dated May 1, 2008.


SAM R. CUMMINGS
UNITED STATES DISTRICT COURT

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
SAN ANGELO DIVISION

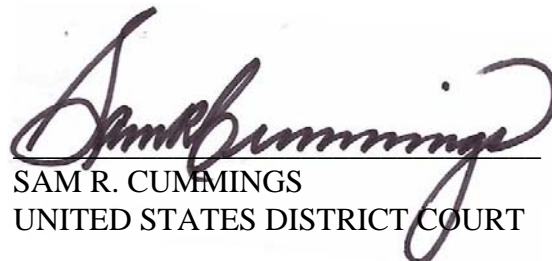
TOMMIE L. GOMEZ,)	
)	
Plaintiff,)	
)	
v.)	
)	
MERCK & COMPANY, INC.,)	
)	Civil Action No. 6:08-CV-017-C
Defendant.)	ECF

ORDER

The Court has been notified that the conditional transfer order filed in MDL-1789, In re Fosamax Products Liability Litigation, of the above-referenced matter to the Southern District of New York, became effective. To manage the Court's docket more efficiently, the above-styled and -numbered cause is administratively closed without prejudice to its being reopened if the case is transferred back to this Court.

SO ORDERED.

Dated May 21, 2008.


SAM R. CUMMINGS
UNITED STATES DISTRICT COURT

on
MULTIDISTRICT LITIGATION

CHAIRMAN:
Judge John G. Heyburn II
United States District Court
Western District of Kentucky

MEMBERS:
Judge D. Lowell Jensen
United States District Court
Northern District of California

Judge J. Frederick Motz
United States District Court
District of Maryland

Judge Robert L. Miller, Jr.
United States District Court
Northern District of Indiana

Judge Kathryn H. Vratil
United States District Court
District of Kansas

Judge David R. Hansen
United States Court of Appeals
Eighth Circuit

Judge Anthony J. Scirica
United States Court of Appeals
Third Circuit

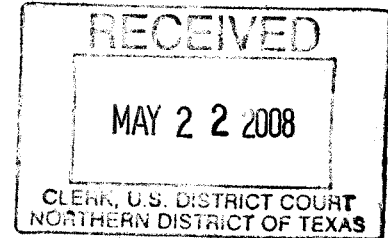
DIRECT REPLY TO:

Jeffery N. Lüthi
Clerk of the Panel
One Columbus Circle, NE
Thurgood Marshall Federal
Judiciary Building
Room G-255, North Lobby
Washington, D.C. 20002

Telephone: [202] 502-2800
Fax: [202] 502-2888
<http://www.jpml.uscourts.gov>

May 19, 2008

J. Michael McMahon, Clerk
Daniel Patrick Moynihan U.S. Courthouse
500 Pearl Street
New York, NY 10007-1312



Re: MDL No. 1789 -- IN RE: Fosamax Products Liability Litigation

(See Attached CTO-54)

Dear Mr. McMahon:

I am enclosing a certified copy and one additional copy of a conditional transfer order filed by the Panel in the above-captioned matter on May 1, 2008. As stipulated in Rule 7.4(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), transmittal of the order has been stayed 15 days to give any party an opportunity to oppose the transfer. The 15-day period has now elapsed, no opposition was received, and the order is directed to you for filing.

The Panel's governing statute, 28 U.S.C. § 1407, requires that the transferee clerk "...transmit a certified copy of the Panel's order to transfer to the clerk of the district court from which the action is being transferred."

A list of involved counsel is attached.

Very truly,

Jeffery N. Lüthi
Clerk of the Panel

By Dana R. Stewart
Deputy Clerk

Attachment

cc: Transferee Judge: Judge John F. Keenan
Transferor Judges: Judge David K. Duncan; Judge Samuel R. Cummings
Transferor Clerks: Richard H. Weare; Karen S. Mitchell

Inasmuch as no objection is pending at this time, the stay is lifted.

MAY 19 2008

CLERK'S OFFICE
JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

MAY - 1 2008

FILED
CLERK'S OFFICE

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION

Vicki Weeks v. Merck & Co., Inc.,)	
D. Arizona, C.A. No. 2:08-623)	MDL No. 1789
Tommie L. Gomez v. Merck & Co., Inc.,)	
N.D. Texas, C.A. No. 6:08-17)	

CONDITIONAL TRANSFER ORDER (CTO-54)

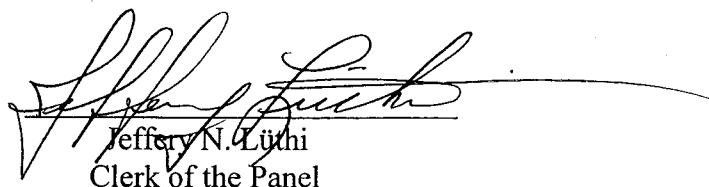
On August 16, 2006, the Panel transferred four civil actions to the United States District Court for the Southern District of New York for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* 444 F.Supp.2d 1347 (J.P.M.L. 2006). Since that time, 123 additional actions have been transferred to the Southern District of New York. With the consent of that court, all such actions have been assigned to the Honorable John F. Keenan.

It appears that the actions on this conditional transfer order involve questions of fact that are common to the actions previously transferred to the Southern District of New York and assigned to Judge Keenan.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), these actions are transferred under 28 U.S.C. § 1407 to the Southern District of New York for the reasons stated in the order of August 16, 2006, and, with the consent of that court, assigned to the Honorable John F. Keenan.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Southern District of New York. The transmittal of this order to said Clerk shall be stayed 15 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 15-day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:


Jeffery N. Lüthi
Clerk of the Panel

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Inasmuch as the stay is pending at this time, the stay is lifted.

MAY 19 2008

CLERK'S OFFICE
JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

JUDGE KEENAN

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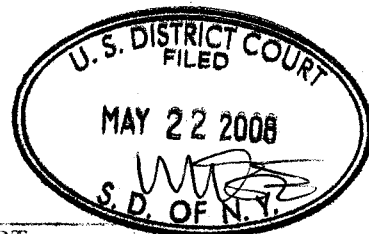
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MAY - 1 2008

FILED
CLERK'S OFFICE

4775

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION



IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION COURT
NORTHERN DISTRICT OF TEXAS

Vicki Weeks v. Merck & Co., Inc.,
D. Arizona, C.A. No. 2:08-623

2 Tommie L. Gomez v. Merck & Co., Inc.,
N.D. Texas, C.A. No. 6:08-17

FILED

JUN - 2 2008

CLERK, U.S. DISTRICT COURT
Deputy

MDL No. 1789

FILED
S.D.N.Y.
SDNY
s/n

CONDITIONAL TRANSFER ORDER (CTO-54)

U.S. DISTRICT COURT
FILED
2008 MAY 23
S.D. OF N.Y.

On August 16, 2006, the Panel transferred four civil actions to the United States District Court for the Southern District of New York for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. See 444 F.Supp.2d 1347 (J.P.M.L. 2006). Since that time, 123 additional actions have been transferred to the Southern District of New York. With the consent of that court, all such actions have been assigned to the Honorable John F. Keenan.

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A CERTIFIED TRUE COPY

MAY 19 2008

ATTEST
FOR THE JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

FOR THE PANEL:

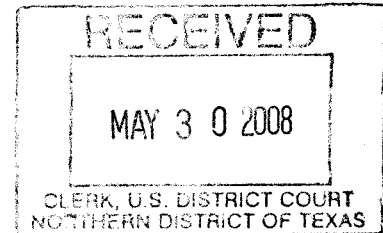
Jeffery N. Luthi
Jeffery N. Luthi
Clerk of the Panel

J. MICHAEL McMAHON,

CLERK

Catherine Lapree
BY
DEPUTY CLERK

UNITED STATES DISTRICT COURT
Southern District of New York
Office of the Clerk
500 Pearl Street
New York, N.Y. 10007
(212)805-0136



J. Michael McMahon
Clerk
NORTHERN DISTRICT OF TEXAS

Date: 05/22/2008

In Re: FOSAMAX PRODUCTS

MDL 1789

Your Docket #
6:08-17

S.D. OF N.Y.
08 CV 4775

Dear Sir:

Enclosed is a certified copy of the order of the Judicial Panel on Multidistrict Litigation, transferring the above entitled action presently pending in your court, to the Southern District of New York and assigned to Judge KEENAN for coordinated or consolidated pretrial processing pursuant to 28 USC 1407.

Please return the copy of this letter when transmitting YOUR FILE and a CERTIFIED COPY OF THE DOCKET SHEET.

Sincerely,
J. Michael McMahon

By: PHYLLIS ADAMIK
MDL Unit
(212) 805-0646

0638

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

Division: San Angelo
33 East Twohig Street Room 202
San Angelo, TX. 76903-6451

June 2, 2008

Clerk of Court
Southern District of New York
500 Pearl Street
New York, NY 10007

SUBJECT: 6:08-CV-017-C, Gomez v Merck & Co., Inc.; MDL 1789, In Re: Fosamax Products

Dear Deputy Clerk:

The above action has been transferred to your court.

Enclosed is a certified copy of the transfer order and docket sheet. You may access electronically filed documents at our DCN CM/ECF web address: <https://ecf.txnd.uscourts.gov>. A guest login and password may be found on our website at: http://ntnet.txnd.circ5.dcn/pdf/irc/guest_login.pdf.

Once logged into our CM/ECF database, you can query the case and download or print the PDFs for your court's file. If you find our headers at the top of each document to be a problem, they can be removed by going through Utilities, Maintain Your Account, and turning off the PDF Header before you download or print the documents.

Any documents not available electronically are enclosed in paper format.

Please acknowledge receipt of the certified copy of the transfer order, docket sheet and original documents, if any, by email to the Intake Section of the appropriate division:

TXNDml_San Angelo

Please reference our case number and brief style in the subject of your email acknowledgment.

Sincerely,
KAREN MITCHELL
Clerk of Court